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# **Numbers in Regulatory Intermediation; Exploring the role of performance measurement between legitimacy and compliance**

## **Abstract**

Much regulatory intermediation (RI) has come to entail forms of calculation and performance measurement. In this paper, we analyze the role of performance measurement in regulatory intermediation in a transnational multi-stakeholder setting where intermediation lacks an official mandate. We do this through a study of the Access to Medicine Index, which ranks pharmaceutical companies in terms of their access to medicine policies and practices in developing countries. We conceptualize multi-stakeholder intermediaries as “second order rule-makers” reconciling diverse and often competing implicit and explicit rules across the governance field. We then detail various intermediation roles of performance measurement between attaining input & output legitimacy and enticing compliance among targets. Our case demonstrates how the selective formalization of measurement processes, and the related ability to move back and forth from the role of intermediary to that of “ad hoc rule-maker”, are important conditions for achieving and maintaining legitimacy. Furthermore, it shows that in multi-stakeholder intermediaries that rely on performance measurement, compliance by targets depends on the uptake of performance information by powerful constituencies. This illustrates how addressing legitimacy concerns and enticing compliance through performance measurement should be examined as co-emerging processes.

**Keywords:** regulatory intermediation, performance measurement, legitimacy, compliance, access to medicine

## 1. Introduction

The shift from state led regulation to regulation by transnational communities comprising states, intergovernmental organizations (IGOs) and private organizations (Djelic & Quack 2010) has seen the rise of a fast expanding set of roles and activities in global governance termed as regulatory intermediation (Abbott *et al.* 2017b). For a vast number of regulatory issues an ecosystem of intermediaries extend the reach and capabilities of regulators (Abbott *et al.* 2017b). These intermediaries can enable, facilitate and shape regulation by contributing to different underlying processes such as agenda-setting, negotiation, translation, adaptation and diffusion of rules, implementation, audit, monitoring and enforcement. Regulatory intermediaries often support the creation of the conditions for the “transparency” invited by regulators (Abbott & Snidal 2009; Garsten & De Montoya 2008) and, importantly, devise diverse types of “soft” pressure for compliance with the rules (Abbott *et al.* 2014).

Intermediaries often compete for relevance in order to carve out a space for themselves in the transnational community they aim to associate with, and to sustain their positioning therein (Buthe 2010). Their legitimacy is usually seen to depend on pluralism and inclusiveness (input legitimacy), procedural fairness, transparency and impartiality (throughput or procedural legitimacy), and with the effectiveness and diffusion of the rules they seek to promote (output legitimacy) (Mayntz 2010; Mena & Palazzo 2012; Quack 2010; Tamm Hallström & Boström 2010).

Given the absence of “hard” sanctioning powers which characterizes non-state regulatory processes in transnational governance, the rules which intermediaries are involved in promoting frequently take the form of voluntary standards and best practices. The adoption of such standards and best practices by targets is usually achieved by means of reputational and competitive pressures, which intermediaries help exercise directly or indirectly, by enabling

others such as civil society organizations to mobilize those market-based compliance mechanisms (Bartley 2007; Overdevest 2010).

These pressures for compliance are exercised through an increasing array of expert practices such as accounting, audit, certification, performance measurement, to name just a few. Such practices, some of which are the hallmark of professions such as accountancy while others remain weakly professionalized, are at the core of much regulatory intermediation. Related tools like performance indicators, ratings, rankings, indices, league tables, scorecards, social labels and the like (Espeland 2015; Merry *et al.* 2012; Rottenburg *et al.* 2015), are used by many intermediaries to evaluate and monitor regulatory targets and to incite them to move towards compliance.

Performance measurement, in particular, has become a central feature of contemporary regulatory governance (Malito *et al.* 2018) and an increasingly widespread way of “knowing” and “judging” regulatory targets, both for the purposes of what counts in this context as rule-making (e.g. defining standards and best practices by means of key performance indicators) and for the purposes of monitoring compliance (measuring the performance achieved for each indicator). Performance measurement and the production and use of indicators is not just a feature of nation states and their agencies, but underlies the entire expanding galaxy of regulatory governance, both nationally and transnationally. International governmental organizations (IGOs) such as World Bank or United Nations, non-governmental organizations (NGOs) and advocacy groups, monitoring bodies involved in the assessment and enforcement of standards, global business and investor groups, expert communities more broadly, have all become heavy users and producers of indicators (Davis *et al.* 2012; Malito *et al.* 2018; Rottenburg *et al.* 2015). In the case of transnational multi-stakeholder private governance initiatives such as the one studied here, compliance (via the transparency ostensibly achieved through performance measurement) and monitoring (via various types of assurance and audit

practices resting on the measurement of performance outcomes) are often achieved via intermediaries, typically NGOs, assurance and consulting firms, or expert groups (Fransen & LeBaron this issue; Mena *et al.* this issue).

When mobilized as part of transnational multi-stakeholder initiatives, especially if stakeholders are divided, performance measurement and quantification can easily become vehicles of conflict as well as mechanisms through which closure to controversies is achieved in the name of the objectivity and rigor typically ascribed to numbers (Porter 1996). Performance metrics can be powerful ways of creating the relative consensus or “reasonable disagreement” (Mena & Palazzo 2012) that multi-stakeholder initiatives depend upon, yet the relationship between the use of metrics and the legitimacy of the regulatory processes they underpin, and its implications for compliance, remain far from settled.

In this paper, we tackle such issues through the examination of a transnational multi-stakeholder initiative based on performance measurement: a ranking within the pharmaceutical industry known as the Access to Medicine Index. This ranking, through 69 performance indicators, measures the extent to which twenty of the largest pharmaceutical companies in the world make their medicines accessible to patients in developing countries.

We trace the work of the analysts who score companies for the purposes of this ranking, acting as intermediaries for the particular form of civil regulation (Vogel 2008) represented by this initiative. We discuss the formulation of indicators and ranking methodology based on consensus-building among stakeholders as a form of “second order rule-making” that attempts to reconcile various existing fragmented implicit and explicit rules. As we detail below, in this process of second order rule-making, contentious issues for which consensus is not achieved are transposed from the formal process of stakeholder consultation to the “unformalized” (Mena *et al.* this issue) backstage of company analysis and performance measurement. In this transposition, performance measurement and scoring practices which are attractive because

they are seen as technical, “cold” and insulated from stakeholder politics provide this multi-stakeholder initiative with much needed legitimacy. However, performance measurement becomes in turn “heated up” by absorbing some residual unresolved conflict in the stakeholder base.

In this way, analysts who act as intermediaries when monitoring company performance occasionally play the role of ad-hoc rule-makers when interpreting and reformulating scoring guidelines and measuring company performance. We thus identify a source of role hybridization for intermediaries (Havinga & Verbruggen 2017), which in our case is not so much a function of the specific relationships entertained in complex governance architectures (where a certain intermediary may be a regulator vis-a`-vis certain actors and a target vis-a`-vis others), but descends from the need to manage conflict in contentious multi-stakeholder initiatives.

Furthermore, our case shows that multi-stakeholder intermediation based on the periodic release of performance information about targets depends on the uptake and consumption of such information by powerful constituencies (influential Non-Governmental Organizations (NGOs), companies themselves, Intergovernmental Organizations (IGOs) such as the World Health Organization (WHO), and especially actual and prospective investors), so that those performance measures can attain regulatory power and motivate compliance among targets. Reliance on performance measures thus tends to make legitimacy (in terms of wide participation of those constituencies in producing and consuming performance information about targets) a continuing concern for multi-stakeholder intermediaries even after they become well-established in the regulatory field. This ongoing importance of legitimacy as a precondition for compliance seems to differentiate multi-stakeholder intermediation based on performance measurement from other instances of transnational regulation (Botzem & Dobusch 2012; Mayntz 2010).

The rest of this paper is organized as follows. In the next section, we position this study in the context of this special issue and review current debates on the relationship between different types of legitimacy and between legitimacy and compliance. We then discuss the relevance of performance measurement for regulatory intermediation, especially in the context of private multi-stakeholder initiatives. The following section illustrates our empirical site and data sources. In the subsequent empirical analysis, we focus on the performance measurement done by company analysts in their diverse intermediation roles as they produce the Access to Medicine Index. In the final section, we discuss performance measurement as a form of regulatory intermediation where measurement processes mediate the tension between the formal and informal side of intermediation, between input and output legitimacy, and between the needs of legitimacy and those of enticing compliance.

## **2. Literature review**

### *2.3 Regulatory intermediation, legitimacy and compliance*

The scholarship on regulatory intermediaries has explored a diverse set of intermediary roles in regulatory fields, ranging from translation and adaptation of rules to coordination, and assistance with auditing and compliance (Abbott *et al.* 2017). Recent contributions to this literature have shown how regulatory roles are fluid and “chameleonic”, and that in different times and spaces the same organization can adopt different roles (Havinga & Verbruggen 2017). Targets at times take on regulatory roles (e.g. corporations involved in governance schemes, in the spirit of the UN Global Compact) and intermediaries succeed in driving rule-making agendas (Havinga & Verbruggen 2017; Van der Heijden 2017). Regulators, intermediaries and targets also engage in different processes of knowledge exchange and feedback, with various implications of such feedback for regulation (Auld & Renckens 2017).

Given the lack of an official mandate that characterizes most regulation in transnational governance, the “legitimacy deficit” usually ascribed to transnational regulators (Menon &

Weatherill 2008; Scharpf 1999) may also be attributed to intermediaries. The relationship between the legitimacy of the “inputs” of regulatory work and how its effects and “outputs” are perceived, in particular, has recently received substantial attention (Mayntz 2010; Mena & Palazzo 2012; Quack 2010; Scharpf 1999; Tamm Hallström & Boström 2010). Input legitimacy in global governance relies primarily on democratic rituals of participation of concerned constituencies in the regulatory process (Mayntz 2010). Expertise is frequently mentioned as another source of input legitimacy (Mena & Palazzo 2012; Quack 2010). Output legitimacy, on the other hand, is related to the perceived effectiveness of regulation (Mayntz 2010; Mena & Palazzo 2012; Scharpf 1999), a precondition for the diffusion and adoption of rules (Botzem & Dobusch 2012). Throughput or process legitimacy is seen to rest instead on the fairness, impartiality and transparency of the regulatory process. Input and throughput legitimacy are often collapsed (Botzem & Dobusch 2012; Mayntz 2010; Mena & Palazzo 2012). Scharpf refers to them as “formal legitimacy”, whereas he describes output legitimacy as “substantive legitimacy” (1999). These two types of legitimacy are seen as related (Mayntz 2010) and have been shown to be variously interdependent in cycles of rule formation and diffusion (Botzem & Dobusch 2012).

Botzem and Dobusch examine the circular relation between input and output legitimacy. Their study of the International Accounting Standards Board (IASB) illustrates how at an early stage of the standardization process, when standards were not yet fully formed and the standardization process was still controversial, great emphasis was placed on input legitimacy through stakeholder participation. This wide participation also meant that the standards being drafted were a collection of somewhat heterogeneous elements, which limited their perceived usefulness and thus output legitimacy. Over time, the vagueness and incomplete formalization of the standards allowed for gradual adjustments and modifications. These, coupled with the ability of the IASB to reduce participation and become an “expert-oriented standard setter”



(2012: 751) and with the support it received from a range of influential third parties, progressively led to greater output legitimacy, which the authors describe especially in terms of adoption and diffusion of the standards.

Botzem and Dobusch conclude that input legitimacy at early stages can foster later diffusion and thus output legitimacy of the standards, but that over time output legitimacy tends to partly replace input legitimacy. In their analysis, input legitimacy may clash with output legitimacy (the initial heterogeneity of standards due to pluralism made them perceived as less useful), but can also increase the chances of later diffusion (by involving a large number of stakeholders and thus potential adopters in early stages). Input legitimacy concerns may also lead to rules (standards) becoming progressively more abstract and open to multiple interpretations. This limited formalization can be a condition for their wider acceptance and thus output legitimacy (see also Mena *et al.* this issue).

Referring to Weber's work on legitimacy, Mayntz (2010) further elaborates on the relationship between input and output legitimacy on the one hand and effectiveness of the regulatory regime and compliance by targets on the other. Referring mainly to the example of the national adoption of EU, GATT or WTO policies, she argues that legitimacy may not be essential for achieving compliance. Mayntz observes that compliance frequently depends on factors other than legitimacy, such as habit, interest calculations or fear of the reputational consequences of non-compliance. She argues that "[a]t least in the short run, little legitimacy is needed to uphold a regime, legal or not, that is able to reward and to punish" (p. 13)<sup>1</sup>.

However, Mayntz is basing her discussion mainly on the example of official and long-established IGOs such as the EU, GATT or WTO. The IASB discussed by Botzem & Dobusch is an instance of a private regulator whose initial standing vis-a`-vis the national states expected

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<sup>1</sup> Mayntz suggests that "It is the normative philosophical stance of political scientists that makes them enquire into legitimacy, rather than their empirical interest in the sources of compliance" (2010: 16).

to endorse its standards was quite fragile, and thus unlikely to be in the position to “reward and punish”. Given the diversity of regulators and intermediaries which characterizes contemporary governance, the question of the link between legitimacy and compliance, as Mayntz argues, is ultimately an empirical one.

In their editorial for this special issue, Mena *et. al.* highlight two crucial aspects of regulatory intermediation in transnational governance: the presence or absence of an official mandate from a rule-maker and the degree of formalization of regulatory intermediation procedures. They argue that these two dimensions define the type of intermediation likely to emerge in private regulation initiatives, and that intermediation may change its characters and properties depending on how it evolves along the lines of such dimensions.

Mena *et al.* argue that intermediation is to be seen as an emergent process which can develop in unexpected directions and whose unfolding needs to be analyzed beyond formal structural features such as the existence of an official mandate and the codified nature of the intermediation process. In particular, Mena *et al.* point to the cognitive and material dimension of intermediation – how tacit or implicit norms are progressively codified and inscribed in some material artefact such as a code, or else kept “unformalized” – as key to understanding how the meaning of rules is negotiated, stabilized or de-stabilized over time and across changing constituencies.

Our study follows these lines of argument by examining the role of formalization in the interplay between input and output legitimacy, and between legitimacy and compliance. We analyze an “unofficial”, “beneficiary-related” (Monciardini & Conaldi this issue), “non-delegated rule intermediary” (Marx *et. al.* 2017) in its efforts to construct for itself a “stakeholder mandate”. We detail how these efforts have been shaped by the development of performance indicators and scoring guidelines with different degrees of formalization, where

such guidelines provide a flexible mechanism to mediate between polarized stakeholder views while at the same optimizing the possibility of compliance by the targets.

## *2.2 Regulatory intermediation and governance by indicators*

The rapid proliferation of indicators, rankings and ratings in the polity during the past few decades (Davis *et al.* 2012; Malito *et al.* 2018; Rottenburg *et al.* 2015) speaks of a calculative turn in regulation and governance. For example, a host of “regulatory rankings” (Mehrpooya & Samiolo 2016) now use performance measurement and benchmarking as a basis for understanding and promoting company compliance with stakeholder-defined standards and best practices: Access to Nutrition Index, Access to Seeds Index, Responsible Mining Index, Access to Vaccines Index, Corporate Human Rights Benchmark, and Access to Medicine Index (studied here).

Governance by indicators, however, is far from uncontroversial or fully understood (Davis *et al.* 2012; Rottenburg *et al.* 2015). In broad terms, the use of quantification in governance speaks of the expanding cultural authority of accounting and quantification in the world polity (Drori *et al.* 2006; Meyer 1986; Jang 2006). Usually associated with transparency agendas, quantification and performance measurement can confer legitimacy to rule-makers and intermediaries because of their presumed scientificity and impersonality (Porter 1996). Quantification carries a promise of objectivity (Porter 1996) and thus democratization (Espeland & Stevens 1998), as well as being ostensibly portable and comparable on a large scale – the quintessential way of “governing at a distance” (Rose & Miller 1992), and thus particularly appealing in those transnational governance initiatives which seek to achieve transparency and comparability of global firms.

Yet the processes of quantification and the underlying efforts to “govern by numbers” (Miller 2008; Rose 1991) in spaces of global governance are rarely transparent and have received relatively little academic attention compared to the empirical scale of the

phenomenon. As Rottenburg and Merry put it, the spread of quantification in governance raises questions concerning “the ways we set the norms we wish to follow, the technologies and instruments we regard as indispensable for organising collective life, and the role numeric representation should play in contemporary world orders” (2015: 1-2). How performance indicators are produced, validated and disseminated, and the enrolment of such “calculative knowledge” in various forms of regulation and regulatory instruments, are issues that require much more attention than granted so far (Malito *et al.* 2018). As Davis *et al.* (2012: 4) put it, the use of indicators “has the potential to alter the forms, the exercise, and perhaps even the distributions of power in certain spheres of global governance”; it opens a set of new questions:

“How does the use of indicators in global governance change the nature of standard-setting and decision-making?,” “How does it affect the distribution of power between and among those who govern and those who are governed?,” “What is the nature of responses to the exercises of power through indicators, including forms of contestation and attempts to regulate the production or use of indicators?”

Questions such as these have a bearing on our understanding of regulatory intermediation. In the space of transnational multi-stakeholder regulation, private regulators tend to use intermediaries to monitor compliance with standards and best practices, yet such monitoring inevitably requires to interpret and redefine (often through forms of quantification alongside qualification) such best practices and standards in the context of the individual circumstances of the organizations being monitored. Here the role of regulator and that of intermediary tend to blend, and quantification is at play in and mediates both roles.

This blending of intermediation and regulation in the process of performance measurement allows much needed flexibility in the interpretation of actual and desired company performance, along two key dimensions. First, flexibility to set performance benchmarks that can be acceptable to different stakeholders (in our case, by combining relative and absolute benchmarks), thus supporting the management of a polarized stakeholder base and input legitimacy. Second, flexibility to adapt benchmarks in the light of observed company

behavior so as to maximize the possibility of compliance (by modifying scoring guidelines so as to highlight attainable performance improvements), thus contributing to the effectiveness of this initiative and output legitimacy. It is to such performance measurement processes as a form of regulatory intermediation in the contentious field of access to medicine that we now turn.

### **3. Empirical setting: The Access to Medicine Index as regulatory intermediation**

Access to medicine in poor countries and communities, and its tension with commercial gains from the sales of medicines, is a centuries-old concern. Since 1994, the ratification of the Trade-Related aspects of Intellectual Property Rights (TRIPS) at the World Trade Organization (WTO) has forced all WTO member countries to create regulatory platforms and compliance mechanisms to protect intellectual property through patents. The TRIPS agreement implied that drugs and other products under patent could remain under the exclusive control of the patent holder for the period of the patent's validity (typically 20 to 25 years). As a consequence, pharmaceutical companies began paying increasing attention to emerging markets (t Hoen et al. 2003). The TRIPS agreement is said to have caused significant price increases and decreased supply of patented products to emerging markets (Grace 2004). This has been concurrent with the emergence of HIV/AIDS as a key global health concern, especially in poor countries, which contributed to increase in the mobilization of civil society around access to medicines (Greene 2011).

Debates in this field are have tended to be highly conflictual, and litigation endemic (Morris 2010). Besides patents, other contentious issues include the pharmaceutical industry's efforts in researching "neglected tropical diseases" which occur almost exclusively in poor countries (where pharmaceutical markets are frequently unviable), its role in providing affordable prices, and its marketing and lobbying ethics in low and medium-income countries.

The WHO, as the primary transnational regulator in this area, has played a central role in providing the main regulatory infrastructure for the access to medicine field by defining need

priorities (in the form of the “Essential Drugs List”) and by publishing the global burden of diseases database (based on Disability-Adjusted Life Year lost to a disease), which quantifies the health burden of different diseases in countries across the world. The introduction of the United Nations Millennium Development Goals (MDG) in 2000 and of the Sustainable Development Goals (SDG) in 2015 have been further milestones in defining the access to medicine problem, and in delineating the role of the pharmaceutical companies in helping address this “gap” (WHO 2014)<sup>2</sup>.

In this expanding transnational regulatory field, besides IGOs such as the WHO and the UN, other international and national organizations compete and/or collaborate towards adopting regulatory roles and orchestrating the regulatory field (Abbott *et al.* 2014). These include, as powerful funders, national development agencies – especially the Department for International Development (DFID) of the United Kingdom and USAID – and private foundations such as the Bill & Melinda Gates Foundation, the Clinton Foundation and the Wellcome Trust. In addition, NGOs such as Doctors Without Borders and Health Action International (HAI) are vocal in this field, seeking to diffuse their own narrative about the Access to Medicine problem and the role of the pharmaceutical industry therein. It is in this ecosystem of overlapping rule-makers that the Access to Medicine Foundation was launched in 2005. Its key regulatory product is a ranking known as the Access to Medicine Index. The first bi-annual index was launched in 2008 and the sixth iteration is under way at the time of writing.

Each Index cycle of two years includes one year of stakeholder consultations aimed at updating the Index methodology, including an online survey, several stakeholder events and

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<sup>2</sup> MDG Target 8.E: In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries. SDG Goal 3: To achieve universal health coverage to include access to essential medicines and vaccines.

discussions about contentious issues at the “Expert Review Committee” (ERC), which includes representatives from each stakeholder group (see Appendix II).

The latest iteration of the Index (2016) consists of 69 indicators, each accompanied by scoring guidelines to be used by analysts when measuring company performance. Each indicator is assigned a weight based on its perceived quality and correlation with the underlying goal of improving access to medicine. The indicators are classified under seven Technical Areas:

- General Access to Medicine Management
- Market Influence & Compliance
- Research & Development
- Pricing, Manufacturing & Distribution
- Patents & Licensing
- Capacity Building
- Product Donations.

**[Enter Figure 1 about here]**

Indicators under each technical area are categorized in the four groups of commitments (policy statements), transparency (public disclosure/reporting), performance (output and outcome indicators) and innovation (unique in the sector initiatives) indicators. Following the finalization of the methodology and its release, a group of analysts engages in data collection, analysis, scoring and ranking.

Since 2009, thanks to multi-year funding from the Bill & Melinda Gates Foundation, followed by UK Department for International Development (DFID) and the Dutch Ministry of Foreign Affairs, the Index has become a central reference point for evaluating large companies’ policies and actions related to access to medicines. The Foundation’s (and the Index’s) success has been such that it is now a key source of knowledge for global debates in this area (e.g. by contributing to major policy documents issued by the WHO and the UN).

#### **4. Sources and materials**

This study covers the development of the Access to Medicine Index from 2005 to 2016. Our sources comprise of documentary evidence, participant observation notes and interviews. Documentary evidence includes press releases, news and media articles, minutes of meetings and outputs from stakeholder consultations (such as online stakeholder surveys conducted in 2009 and 2011, four stakeholder meetings held in 2009 and 2010, one meeting with NGOs in Nairobi, Kenya in 2010, two stakeholder meetings, two meetings with the pharmaceutical industry and two meetings with investors in 2011).

One of the *authors (name withheld for the blind review process)* was a reviewer for Index 2008 and later became the Index Project Manager, employed by the Access to Medicine Foundation's subcontractor – Innovest (later MSCI) – from November 2009 to June 2011. From June 2011 up until November 2012 he was a member of the editorial board and steering committee for Index 2012. Since September 2012 he has been doing “participant observation” (Jorgensen 1989), taking notes of his engagements with the Foundation.

We also conducted 24 semi-structured interviews, which were coded and transcribed. Interviewees included the Foundation's founder, two of its former CEOs, two pharmaceutical company representatives, two NGO representatives, a UK Department for International Development (DFID - major funder of the Foundation) program manager, a WHO official involved in developing the Index since 2008, the chair of ERC for Index 2010 and 2012, two former managers of Innovest Strategic Value Advisors, the project managers for Index 2008, Index 2012, Index 2014 and Index 2016, the Foundation's deputy director of strategy since 2015 and members of the Index 2008, 2010, 2012, 2014 and 2016 analyst teams.

## **5. Performance measurement, between legitimacy and compliance**

### *5.1 Input legitimacy*



The Access to Medicine Foundation was launched in 2004 by Wim Leereveld, with the aim of enticing the pharmaceutical industry to do more for access to medicine. Leereveld describes his motivation to launch the Index along the following lines (Interview 2013):

I realized I had a possibility to bring everyone at the table by organizing a sort of stakeholder consensus, a sort of common agenda – what the world wanted – and at the same time I knew the competitiveness of this world, of these companies.

The agenda was to overcome the bitter confrontation between the industry and other organizations, such as some vocal NGOs, which had paralyzed the access to medicine debate. The Index was proposed as a measurement tool that could carve out, and operate within, a space of consensus. Discordant views on what the industry needs to do to improve access to medicine are seen as “problematic because the pharmaceutical industry lacks concrete guidance on how to best respond to societal pressure. Moreover, external stakeholders cannot hold the industry to account without using mutually-agreed-upon standards” (De Felice 2016).

Operating with such an agenda in the conflict-ridden space of access to medicine was a daring enterprise for what was essentially, in its early stages, a one-man initiative – an NGO with only one full-time employee (its founder) which received its first major multi-year funding from the Bill & Melinda Gates Foundation only in 2009. In its early days, the Foundation was a rather obscure “unofficial” intermediary (Mena *et. al.* this issue). It soon became clear to Leereveld, especially after receiving advice from a United Nations official, that in order to move the consensus-building agenda forward some formal stakeholder consultation had to be organized (Interview with Leereveld 2013). In 2006 and 2007, the Foundation and the company hired to develop the Index convened several stakeholder roundtables. The Foundation released a stakeholder consultation report and then an industry consultation report which served as bases for the development of the first Access to Medicine Index in 2008.

Despite this first milestone, following the launch of Index 2008 the Foundation faced criticism both from the industry and some international NGOs with regards to its stakeholder

consultation process. In response to this criticism, for the following iteration of the Index (issued in 2010) the Foundation organized a stakeholder advisory body, named the Expert Review Committee, that was to oversee methodological development and decide on contentious issues. The stakeholders included representatives of the research-based pharmaceutical industry, the generics sector, investors, academia, Western and Southern governments, and IGOs – namely the WHO (Appendix II includes the ERC structure for Index 2012).

This was the start of the Foundation’s attempt to formalize a “second order rule-making” apparatus that would reconcile the competing and at times conflicting expectations and rules set for pharmaceutical companies by different constituencies (the “first order rule-makers”) into a set of consensual rules, in the guise of performance indicators. Company analysts<sup>3</sup> would then focus on the intermediary role of collecting data and scoring companies with the combined goals of monitoring compliance and also enticing compliance through their scoring approach. At this early stage, stakeholder participation and consultation were considered essential to the Foundation’s survival and there was an intensification of efforts to achieve input legitimacy, focused on the formalization of a stakeholder mandate and on the informal management of stakeholder conflict.

While the goal of the ERC was to define a space of stakeholder consensus that could provide the Index with a stakeholder mandate and compensate for its lack of an official mandate, achieving such consensus on contentious issues such as patents and competitive practices proved a continuing challenge. Examples of contentious indicators (especially contested by several large pharmaceutical firms) include those against data exclusivity (related to the exclusion of generics manufacturers from the use of clinical trial files of research-based

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<sup>3</sup> Company analysis was originally outsourced by the Foundation to firms like Innovest (later MSCI) and Sustainalytics, whilst from 2014 the Foundation has created its own in house analyst team.

firms), those against the patenting of medicines in the Least Developed Countries, and those endorsing Patent Pooling initiatives (such as UN Medicines Patent Pool). Methodological decisions on such indicators, when they could not be reached within the ERC, were often left to the Foundation and the analyst team. Such issues were moved, in other words, from the formal space of stakeholder consultation to the informal “backstage” of company analysis. In this way, analysts adopted an ad-hoc rule-setting role for those contested issues. The analysts tended to absorb the Foundation’s responsibility of dealing with and balancing the conflicting positions in rule-making that could not be decided in the stakeholder consultation process, and to produce scores that would reconcile those competing demands. This rendering technical of contentious issues helped weather the insoluble conflict that seemed to mark the space of access to medicine, and the “legitimacy deficit” which a small unofficial intermediary cast in this contentious space of immense economic and social stakes was bound to confront in its early days.

The analysis process was formally described as avoiding any form of “politics”; analysts were told they had to operate as “experts” in evidence-based analysis and as politically neutral “stakeholder collectors”. This intense stakeholder intermediation work entailed at times an element of fear (Interview – Index 2010 analyst I):

I mostly feared the companies, which is ironic because the Foundation was our client. I was more scared of the companies, because they know their data better than I do – way better than I ever could, but I depend on the data they send, as well as, obviously, external sources. I had nightmares about making mistakes – but in a positive way, this forces you to make sure everything you’re putting in there is accurate [...] Hot topic areas – areas of dispute between NGOs and companies – were where I was the most scared of making mistakes, just in terms of legally representing them properly.

In attempts to avoid politics and accusations of bias, projecting technical competence played a central role and quantification, in this respect, was paramount. Analysts considered quantified information to be more “dependable” (Index 2010 analyst III) or “scientific” (Interview - Index 2008 Project Manager). As specified by one analyst (Interview - Index 2010

analyst III) there was an implicit assumption that quantified data was more objective and reliable. Quantification, in other words, played a central role in the formalization of the index methodology and was seen as a way to increase its scientificity.

For the purpose of data collection and scoring, the analysts relied on diverse sets of secondary sources ranging from the WHO (for DALYs, patents), Lexis Nexis (for lawsuits), Factiva (for news) and Thomson Reuters (for financial information). This was in addition to the information that companies provided in response to the Foundation's questionnaire, which requested detailed information about their activities that could have implications for access to medicine for "Index Countries" and "Index Diseases" (the geographical and disease scope of the index).

Not all sources were regarded as equal; analysts made a judgment of how credible each source was based on its level of potential bias. Analysts considered information coming from organizations universally regarded as credible such as the WHO as "the gold standard" (Interview – Index 2010 analyst II), whereas they did not necessarily consider local and more activist NGOs as neutral because of their more confrontational attitudes towards the industry. Overall the criterion for inclusion of sources was avoiding stakeholder politics when the issues at hand could not be made technical and addressed in an "evidence based" fashion. Intermediation, at this stage, meant the ability to screen all available sources on the access issues at hand, and ensuring that the sources selected remained scientifically valid, neutral or representative of the wide and often divided stakeholder base of the Index.

This process of reverting to data accuracy and evidence was however not unproblematic. The expert views and scientific sources in many areas were also polarized. Ultimately, "it was about saying, okay, we have got some expert views, they seem to be polarized or inconclusive and we need to take a judgment call on the knowing that there are two quite valid perspectives". (Interview – consultant for Index 2012). Alignment with the main views of, and with trends set

by, key international organizations was a way of securing and stabilizing the analysts' position on contentious issues. In the words of the same interviewee: "what is reassuring I suppose is that the methodology review does seem to be in-line with global health trends I guess, thinking policy trends" (Interview – consultant for Index 2012). Thus, on the one hand contentious rule-making issues had to be resolved in the not fully formalized space of analysts' judgment, but on the other hand alignment with official and formalized policy documents provided this more subjective and informal processes with a safe anchor. Here, a subtle interplay between the formalized and the not-yet-formalized and between the official and the unofficial allowed analysts and the Foundation to maneuver between the conflicting poles of its stakeholder base.

Over the years, stakeholder consultation seems to have become a "cooler" process. First, a range of technical sub-committees (TSC) were introduced with Index 2012 to support the methodology review process and insulate some of the technical issues at stake from the more open stakeholder politics of the ERC. Furthermore, with its increased stability and centrality in the field, the process of scoring companies and the language used by the Foundation more broadly have become much more assertive.

Fear of politics, which permeated the analysis underlying the Index and the tone of Index report, has now been largely tamed. For example, the report for Index 2016 for the first time provides a summary of performance observed within each tier in the ranking, including a section for the lowest ranking companies, in which firms at the bottom are singled out (ATMI 2016). In the early years, the Foundation tended to avoid focusing on the firms at the bottom because it could be seen as negativistic, as a choice of "stick" over "carrot", where the former was deemed to be more "political". Furthermore, the Foundation's tone regarding the industry's overall behavior has become more critical. From the language of "major improvements made" (ATMI 2012:16) in the past Indices, the Foundation can now frame the situation as "progress is slower than many of us would like" (ATMI 2016: 5).

This new confidence vis-a-vis companies in the tone and methodology express the ability to move more freely from the constraints of input legitimacy which threatened the Foundation's survival in its early days, especially with respect to one of its most important stakeholders, the companies, who are the targets of this regulatory initiative but also enablers as suppliers of company data. Nonetheless, the Foundation, despite its now quite stable positioning in the field, continues to maintain its stakeholder consultation infrastructure and its focus on good stakeholder relations. Additionally, it now organizes for each iteration of the Index, several meetings separately with the investors, the companies, the WHO and the local NGOs. Such continued focus on input legitimacy can be explained by the fact that, for the Foundation, the effectiveness of the Index and the compliance of companies depend on whether powerful stakeholders use it in their decision-making, so that pressure will be exercised on the targets. An inclusive stakeholder consultation process and good relations with stakeholders are important preconditions for their continued use of the Index in the governance space and thus fundamental preconditions for output legitimacy, to which we now turn.

## *5.2 Output legitimacy*

Given the diverse and polarized stakeholder base for the Index, notions such as “output” or “effect” mean different things to different stakeholders. While in its communications with funders, NGOs, international organizations and Southern governments the Foundation emphasizes social impact, in its dealing with investors the Foundation primarily emphasizes the business case for access to medicine. The Foundation tends to present the business case for improving a company's position in the ranking by suggesting that such positioning can be seen as a proxy for business success in emerging markets. This is while it normatively describes the provision of affordable, accessible and high quality medicines as part of the “social contract” of pharmaceutical companies (see for example the introductory letter to Index 2016: 5). Claims

of effectiveness have to reconcile different “substantive values” in the stakeholder base (Mayntz 2010), pointing to the mutual entanglement of input and output legitimacy.

In the early days of the Foundation, there was little pressure for proof of impact. The main funders at the time were small NGOs (such as HiVOS, CordAID and Oxfam Novib) and their main emphasis was on matters related to input legitimacy such as inclusion and participation of stakeholders (Interview, chief executive of HiVOS, 2014). Since 2009, with the arrival of the Bill & Melinda Gates Foundation followed by the UK DFID and the Dutch government, there has been an increased emphasis on providing proof of social impact.

Similarly to other intermediaries (Kalfagianni & Pattberg 2014), the Foundation has encountered difficulties in linking its activities, arguably positioned at the “global level”, to improvements in the local realities of healthcare. Access to medicine in the 107 countries currently covered by the Index is affected by numerous factors – such as the local socioeconomic and regulatory situation or the provision of primary healthcare – over which the companies can exert little influence. Such contingencies mean that the industry, even when incentivised by the Index, can only play a partial role in improving “access to medicine”. Nonetheless, constituencies eager to monitor the effectiveness of the Index welcome evidence of indicative changes in the pharmaceutical companies. For example, in its 2013 annual review of the Foundation (based on the Logical Framework), DFID proposes that (DFID 2013):

impact evaluation was not feasible and ... a more upstream approach to showing the impacts of the Index needs to be taken ... Positive behaviour change among companies is to be demonstrated through an independent evaluation, to be completed in 2015.

This funder’s demand for an “upstream approach” is basically about giving up on evaluating effectiveness “downstream” on the target populations, resorting instead to finding “upstream” proxies for effectiveness. Along these lines the Foundation has sought to substantiate its effectiveness by engaging a consulting firm, Foundation Strategy Group (FSG),

to study stakeholder perspectives on the use and impact of the Index<sup>4</sup>. Responding to a survey of multi-stakeholder rankings titled “Rate the Raters”, the Foundation cites the FSG report where it states that the Index (SustainAbility, 2014, p. 2):

provides useful guidance for some Corporate Social Responsibility (CSR) departments as they seek to advance the access agenda internally, and it has influenced reporting – both in terms of the new level of transparency embodied by the Index, and in companies’ proactive communication of a broader range of access issues.

Similarly, the Foundation actively communicates anecdotes linking the Index with company behavior. For example, in a Tweet in 2015, the Foundation highlights that:

In line with [#2014AtMIndex](#) recommendation, [#JNJ](#) w. PHTI expands non-enforce commitment 4 darunavir [#patents](#) <http://ow.ly/MTkGB>

As to providing proof of the business case and financial impact of access to medicine targeted for investors, the Foundation collects evidence that large reputed investors make use of the information provided by the Index, such as analyst reports. Furthermore, the Foundation has compiled a letter signed by a large number of investors stating their belief in the financial materiality of access to medicine and committing to push for the Index’s agenda (ATMF 2016).

These attempts to project at the same time social and financial impact have significant implications for the work of analysts. Company profiles published in the final Index report frequently emphasize both the social and the commercial implications of the companies’ access to medicine related policies and practices. For instance, in an analyst training document for Index 2010, an example is provided for how the analysts should frame the implications of litigation cases:

Such cases, if proven, can bring into question the effectiveness of the company’s reactions to the health hazards of its medications in the emerging markets. Such a weakness not only puts the target populations at risk but also can put at risk the company’s image and stakeholder relationships in the target communities.

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<sup>4</sup> The Foundation has also engaged Erasmus University in Rotterdam to set up an on-going impact assessment for the coming five years, but it remains to be seen whether this assessment will be more successful in identifying downstream effectiveness.



Here, ineffectiveness in addressing health hazards is questioned in relation to both its detrimental effects on the target populations (social case) and also its implications for the company's image and relationships with stakeholders (business case).

However, developing indicators which promote the business case alongside the social one is not always possible. In the Index methodology, there are various indicators that place societal claims on companies. Some of these indicators can also be justified with a business case argument. One example are indicators related to research collaborations addressing emerging markets' needs, where the latter have positive implications both for access to medicine (e.g. addressing neglected diseases) and for market expansion. Other indicators however are based purely on stakeholders' demands with no, or even negative, economic implications for the firms. As an example, there is an indicator that gives a higher score to companies which do not push for protection of their clinical trial data from use by generics companies (termed as "data exclusivity"). This measure is based on the stance of the WHO and international NGOs on the issue and there is no strong business rationale for its inclusion. For most patent-related indicators the business rationale is also weak, as reflected in some comments made in response to a survey conducted by the Foundation in 2011.

Attempts to attain output legitimacy in other words involved "values intermediation" by analysts aimed at appealing and providing proof of impact to constituencies with competing/conflicting value regimes. While the language used avoids claiming direct causality, efforts to provide both proof of social impact (primarily focused on funders) and proof of financial impact (targeting investors) have been intensifying as the Foundation and the governance field of access to medicine have "matured". On the other hand, issues such as expertise, stakeholder inclusion and other dimensions of input legitimacy seem to have become less pressing and more taken for granted.

### *5.3 Enticing compliance – Between competition, stakeholder accountability and learning*

The Index operates principally through three “soft regulatory” processes: motivating competition among companies, enabling stakeholder accountability through transparency and promoting learning and diffusion of best practices by emphasizing and detailing “outstanding” companies and practices.

Producing performance indicators inviting competition implies that analysts have to generate scores, rankings and sub-rankings (on different technical areas) that highlight attainable differences (and thus performance gaps) among companies. When variability in company performance for individual indicators is deemed insufficient, analysts refine the scoring guidelines for the indicator in question in order to be able to further differentiate among companies.

Scoring guidelines enable and facilitate the measurement of company performance as articulated in the description of each indicator. They provide the benchmark for company compliance with the best practices the Index aims to disseminate. As data is collected, based on the observed levels of performance for each indicator, the scoring guidelines for each indicator can be adjusted to ensure a good distribution of scores for each indicator. Often, this means to make differences between performance levels subtler and more nuanced, by differentiating companies at the margin. These marginal differences point to attainable improvements in the performance of adjacent companies, maximizing the possibility of compliance and potentially contributing to the effectiveness of this initiative and thus to its output legitimacy.

To maintain this flexibility in the scoring process, scoring guidelines are not disclosed at the time when the Index methodology report, which includes the updated indicators and scope of analysis for each Index, is published (before data collection). Scoring guidelines are instead published along with the final Index report, after being revised during the analysis process (we

have included a sample indicator accompanied by its scoring guidelines from the Index 2016 final report in Appendix III).

The Index started its life as a relative ranking, initially associating a score of five to best *observed* performance and a score of zero to the lowest observed one. However, this led to maximum and average scores in Index 2008 that some NGOs considered as too high and as a “too positive image of the industry”; the Index was accused of giving “a financial boost to the big brands and their socially conscious investors”, without any “real improvements in access to essential medicine in developing countries” (Reed 2008). Since Index 2010, the methodology has been revised to make it more demanding. Many indicators are now used as absolute rather than relative benchmarks; that is, they measure company performance vis-a`-vis predefined stakeholder expectations rather than already observable best practices. A score of five is more and more often associated with best *expected* performance, effectively making the Index a mix of relative and absolute ranking. As a result, maximum and average scores have been progressively falling.

This brings the index closer to being useful for stakeholder accountability, as NGOs and others aiming to put pressure on companies pointing to what remains to be achieved, can refer to the white space in the Index graphs (measuring the distance between overall company performance and a score of five) in order to put claims on any company and the industry as a whole. In other words, in combining relative and absolute ranking the Index methodology and the work of its analysts effectively mediate between the ability of the Index to work as a tool for competition and as a tool for advocacy and stakeholder accountability, also enhancing the flexibility of this multi-stakeholder initiative vis-a`-vis the needs of its various constituencies its ability to sustain input legitimacy over time.

A third process the Foundation mobilized to achieve compliance was highlighting best practices and “star performers” to motivate a “race to the top” through mimicking and learning

by other companies (similar to Global Compact where learning is central to efforts directed at enticing compliance – see Ruggie (2001)). Compared to the aim of inducing competition, which demands a good distribution of scores, identifying “stars” and best practices requires making certain companies and/or practices stand out. The analysts were responsible to detail outstanding practices in each technical area. These were included separately at the end of each chapter of the report, and illustrated in narrative form. The Foundation further planned a related project to document and detail outstanding practices through a peer reviewed process to ensure their potential for improving access.

The analysts’ attempts to obtain details about outstanding initiatives (such as sales volume for medicines, prices, performance targets, and market strategies) were however frequently challenged by companies’ reluctance to provide such detail, presumably because of the sensitive nature of some of this information and related confidentiality issues. In other words, while stakeholder accountability and learning through best practices require detailed public disclosure, the competitive dimension of the industry and related data confidentiality issues limit such public disclosure. The Foundation uses indicators focused on transparency to pressure companies to cede to public disclosure. Information disclosed to the Foundation without public disclosure is useful only for ranking purposes, supporting competition based on the ranking but not learning among the companies. Therefore, these two key compliance mechanisms – competition and learning from best practice – remained somewhat in tension. Intermediation, in this context, meant enticing disclosure and transparency by means of specific transparency indicators, while at the same time allowing for data protection in all those instances in which transparency was perceived by targets as a threat to the competitive game.

Thus, all three compliance mechanisms at play were supported by the performance measurement work of analysts. These were at times complementary but also tended to partly

conflict. Performance indicators were used to promote each of these mechanisms and to some extent allowed to mediate between them.

## 6. Discussion

The Access to Medicine Foundation provides an interesting example of an emergent “unofficial” intermediary (Mena *et al.* this issue) combining second order rule-making in the guise of stakeholder consultation and indicator design with regulatory intermediation through monitoring targets and enticing compliance by means of performance measurement and ranking. This initiative was launched without delegation or mandate from neither the regulator(s) nor the targets (Marx & Wouters 2017). It rose in a field rampant with conflict, wherein fragmented and polarized attempts at setting the rules for the pharmaceutical companies vis-à-vis the access to medicine problem were made on the one hand by various NGOs and Southern governments and on the other by the industry itself, with the WHO and United Nations promoting broader health policy standards and awareness of the problem.

The intermediation studied here, with performance measurement and benchmarking as its cornerstones, is part and parcel of the broader trend of “trust in numbers” in public life (Porter 1996) as a basis for monitoring, audit and accountability (Garsten & De Montoya 2008; Power 1999). This reliance on transparency based on numbers organized in various devices such as indicators, ratings and rankings (Merry *et al.* 2012; Rottenburg *et al.* 2015) speaks of a calculative turn in regulation and governance, especially evident at the transnational level (Malito *et al.* 2018). Our case foregrounds several ways in which performance measurement can work as a form of regulatory intermediation, variously supporting a multi-stakeholder intermediary’s efforts to achieve and sustain input and output legitimacy and its attempts at enticing compliance among targets, detailed in table 1. (below) and in the remainder of this section.

**[Please insert table 1. about here.]**

### *6.1 Performance measurement, input legitimacy and formalization*

The Foundation's extensive focus on input legitimacy through stakeholder consultation in the early years of the Index was aimed at establishing a stakeholder mandate based on a consensus that would in a way emulate the missing official mandate for its intermediation efforts. The Foundation had to construct and maintain this somewhat fragile mandate through "officialization struggles" aimed at mediating between, and reconciling demands from, several powerful constituencies with more or less formalized claims on the pharmaceutical industry. Through its consensus-building work, the Foundation essentially engaged in "second order rule-making" to reconcile the fragmented rules different stakeholders would like to impose on the industry, and to come up with a consensual agenda or at least a "reasonable disagreement" (Mena & Palazzo 2012).

This case shows that rule-making and intermediation can occur in layers and within multiple and complementary arenas. The WHO sets broad rules regarding the areas of access to medicine need and recommends broad health policies; the NGOs set rules more aligned with more specific societal expectations, aimed primarily at exercising public accountability pressures on companies; the industry sets its own self-regulatory norms and standards. In this context, the Foundation acts both as an intermediary and as a second order rule-maker trying to reconcile different implicit and explicit rules produced by others for the pharmaceutical industry.

This composite picture points to the need to question the notion of rule-maker as a stable category in the R-I-T model (Abbott et al., 2017b; Abbott, Levi-Faur, & Snidal, 2017a). Especially in the context of multi-stakeholder regulatory processes (Fransen 2012; Mena & Palazzo 2012; Tamm Hallström & Boström 2010), focusing on processes of "officialization" rather than taking rule-making as given brings to fore the multiple and shifting locations where

the rules of the game emerge and take hold within the broad apparatus of regulatory governance. Intermediaries can negotiate their mandate with multiple more or less official rule-makers (such as IGOs, NGOs, and even the targets themselves), each involved in producing more or less formalized rules. As the intermediary strengthens its mandate, rules can surface and “solidify”. Intermediation and rule-making thus emerge as mutually constitutive processes which become hard to disentangle empirically. Rule-makers, in turn, face their own officialization challenges, with their mandates shifting in content and strength. In the brave new world of regulatory capitalism (Levi-Faur 2005; Levi-Faur & Jordana 2005), in other words, the polity comprises of a pool of organizations with fragile mandates, mutually relying on each other’s rule making and intermediation roles to emulate the states’ public mandate and to stabilize their positioning.

Input legitimacy has emerged in our case as a crucial part of such “officialization struggles”. It entailed establishing and sustaining the multi-stakeholder consultation processes, as found in the case of other informal intermediaries (Fransen 2012; Gulbrandsen 2008; Mena & Palazzo 2012; Tamm Hallström & Boström 2010). It also required a constant focus on political neutrality and to project the Foundation as a purely “technical” intermediary with no values of its own.

However, the absence of consensus on contentious issues frequently led to transposing those unresolved issues to the informal or not-yet-formalized backstage of company analysis. In this way, analysts had to perform their formalized role as intermediaries, conducting analysis and scoring based on the rules ratified by the ERC, and to simultaneously engage in “ad hoc rule-making” for those contentious issues. This further illustrates how rule-making and regulatory intermediation are frequently intermingled. What we observe in the work of the analysts examined here is not only chameleonic shifts in roles (Havinga & Verbruggen 2017) which depend on the specific relationships entertained in complex governance architectures

(where a certain intermediary may be a regulator vis-à-vis certain actors and a target vis-à-vis others). In contrast, our case points to a deeper, more fundamental and persistent integration and hybridization of those roles.

The instability and incompleteness of the stakeholder “consensus” achieved within the ERC meant that concerns with input legitimacy were present at every step of the analysis process. As shown, especially in the early years, the significant power imbalance between the analyst teams of this informal intermediary and its powerful counterparts, added an element of fear to the work of some, further intensifying attempts to adhere to the principles of evidence, neutrality and objectivity. Quantified information was considered more reliable, replicable, objective and precise. However, as shown, while numbers were the formalized and foregrounded aspects of performance measurement, the challenges of measurement were mostly backgrounded and kept in the informal space of analysis. In addition, some methodological aspects such as the scoring guidelines were formalized and disclosed only at the end of each Index’s cycle, so that the intermediary could maintain flexibility in how it could score companies based on the possibilities and limits of the data received from them.

Analysts had to balance between elements of their work that should and could be projected as solid, reliable and formal, and elements to be kept informal. This selective formalization allowed this unofficial intermediary to deal with contentious issues. Furthermore, this interplay between the formal and the informal and its timing were essential to maintain flexibility in the methodology development process and calibrate the Index as a regulatory tool.

Several other studies have shown how ambiguity and lack of formalization are important to ease the adoption of standards (Rasche 2009; Thérien & Pouliot 2006) in contested policy fields (Best 2005). Our work further contributes to this line of scholarship by foregrounding the importance of attending to the dynamics of formalization (and, by extension, of



backgrounding what needs to be not (yet) formalized (see Mena *et al.* in this issue)) in the work of unofficial intermediaries operating in highly contentious fields of governance. Which parts of the intermediation process are formalized and when such formalization occurs is a constant process of backgrounding and foregrounding which is central to sustaining input and procedural legitimacy. Our case highlights how the formal and informal side of intermediaries' work are not so much stages in a sequence which ends with full formalization, but rather constantly co-emerging processes supporting attempts to operationalize measurement conventions descending from a fragile stakeholder mandate.

## *6.2 Performance measurement and the relation between input, output legitimacy and compliance*

Botzem and Dobusch (2012) point to the circularity of the relationship between input and output legitimacy. They discuss how input legitimacy (stakeholder participation to standard-setting) can initially hamper output legitimacy (adoption of standards), but also how at later stages, as standards take hold, their adoption can be helped by the wide participation base of early stages. They also observe input legitimacy concerns progressively giving way to output legitimacy concerns.

We identify similar dynamics in our case. As the Foundation becomes more established, its focus on output legitimacy increases and input legitimacy becomes progressively less problematic especially vis-à-vis companies. However, unlike the IASB studied by Botzem & Dobusch, which moved from direct stakeholder participation to mere consultation, thus radically changing its basis for input legitimacy from a mix of democratic participation and expertise to pure (private sector) expertise, in our case stakeholder consultation exercises, and dedicated communications with powerful stakeholders such as investors, NGOs, Southern governments and the WHO have continued extensively, even if threats in terms of contestations from such actors have decreased over time.

For companies to care about the Index and to comply with the best practices it promotes, powerful constituencies need to utilize the Index in their decision making and advocacy work. Enforcement can only happen by means of third party pressures. Here stakeholders able to exercise pressure on companies become de-facto intermediaries, further pointing to the constant blurring of roles in the R-I-T model. As a result, stakeholders continue to matter to the Foundation as enablers of compliance. The adoption of the Index as a source of rules for the industry, in other words, can only be on-going and as a result the Foundation needs to reach out to stakeholders on a continuous basis. Conversely, in the case of the IASB studied by Botzem and Dobusch once IFRS are adopted by means of “hard law” endorsement, adoption can be said to have happened once and for all, or for the foreseeable future. In our case input legitimacy and output legitimacy appear to be linked at a fundamental level, as input legitimacy not only facilitates output legitimacy but becomes the key mechanism through which the latter is achieved. Intermediaries relying on the use of the knowledge they produce about targets by a wide set of constituencies to increase the possibility of compliance by targets cannot much reduce their input legitimacy efforts even when they are well-established in the field.

Thus, our case raises an important point in response to Mayntz’ (2010) reflections on the relationship between legitimacy and compliance. Mayntz bases her argument of the overstatement of legitimacy as a condition for compliance on the analysis of European regulation, which is largely official. Our case illustrates the continued importance of input legitimacy in the absence of an official mandate in the case of multi-stakeholder regulation, when the compliance possibilities anticipated by the intermediary are maximized if stakeholders use the knowledge it produces about targets. We agree with Mayntz that compliance by companies may not fundamentally depend on the formal legitimacy of the intermediary, and that it may simply be a function of the extent to which companies feel threatened (e.g. in their reputation) by the actions of the intermediary. However, the type and

dynamics of the “mandate” an intermediary receives, as our case shows, will have consequences in terms of the path through which compliance is pursued, and the role of legitimacy in this, and need to be scrutinized. To be able to influence the targets, the intermediary we study can only work indirectly, via the the recognition and use of its performance information by other stakeholders, and thus legitimacy and compliance remain intimately linked.

## **7. Concluding Remarks**

Our study of the Access to Medicine Index has helped us bring to the fore several aspects of unofficial intermediation based on performance measurement in a multi-stakeholder setting. By seeing this type of intermediation as a process of officialization in which “second order rule-making” by the intermediary contributes to building a stakeholder mandate, we have drawn attention to rule-making and intermediation as mutually constitutive processes, which are more widely distributed and pervasive than an exclusive focus on official forms of intermediation would allow to grasp.

Secondly, we have highlighted the importance of the selective formalization of the performance measurement process for sustaining legitimacy and enticing compliance, where the latter remain more intimately connected than often posited by the literature. As discussed, this is because in our multi-stakeholder initiative based on performance measurement compliance heavily depends on the uptake and use of the performance information by powerful constituencies. Our case ultimately illustrates that addressing legitimacy concerns and developing the potential of rules, in our case best practices captured by performance indicators, for achieving compliance should be investigated as co-emerging processes.

Finally, our focus on performance measurement is evocative of the role of material artefacts – such as written texts, hardware and software, graphs, scorecards, and the like – in regulatory intermediation, so far largely overlooked (Mena *et al.* this issue). Our illustration of

performance measurement as a form of regulatory intermediation, where marginal differences on the zero-five performance scale are used as levers for moving powerful global companies towards compliance, points to the need to trace these more mundane sites and mechanisms of regulatory intermediation beyond the role of human actors, attending to the technological side of regulatory capitalism.

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## Appendix 1 – List of interviewees

Organization	Position held	Role at the Foundation
Access to Medicine Foundation	Founder and CEO	Founded the Foundation in 2005 and since has been involved in various executive and chair positions at the Foundation
	Chief Operating Officer since 2011	Supervised the production of Index 2012 and 2014 and other operations of the Foundation
	Head of Research since 2012	In charge of managing analyst team and production of Index 2012 and 2014
	CEO from November 2008 to December 2010	Supervised Foundation operations during the development of Index 2010
	Deputy Director of Strategy – 2015 to present	Involved in external facing and strategy setting at the Foundation.
MSCI Group	Analyst I for Index 2010	Were hired following the finalization of methodology for the analysis/ranking phase for Index 2010 – from November 2009 to May 2010
	Analyst II for Index 2010	
	Analyst III for Index 2010	Each analyst was responsible for 42 analyzing and scoring five companies and also to specialize in 1-2 technical areas to check the quality of the other analysts' work in this areas.
	Analyst IV for Index 2010	
	Senior analyst	Headed the analyst team at MSCI for Index 2012
MSCI Group – Access to Medicine Foundation	Former analyst at MSCI Group for ATMI 2012 – Analyst at the Foundation since 2012	Analyst for Index 2012 and 2014
Innovest Strategic Value Advisors (later acquired by MSCI Group)	Senior analyst	Project manager and head of analyst team Index 2008
	Former CEO	Involved in discussion leading to the development of Index 2008 and 2010
	Former research Director – 2011-2013 consultant at the Foundation	Liaised with the Foundation and other stakeholders and supervised the development of Index 2008 – from 2010 to

		2012 – responsible for investor advocacy at the Foundation
Health Action International	Executive director	ERC member for ATMI 2012 representing NGOS
HiVOS	Former Program Manager	NGO involved in funding of Index 2008 and 2010 and present in stakeholder meetings for those
Department for International Development (DFID)	Consultant for the Foundation in 2012 and then Program Manager at DFID	Consultant for Index 2012 at Foundation in charge of leading the Foundation's inhouse team and the write-up of the report - in charge of managing relationship/reporting with the Foundation at DFID since 2013
Novartis	Head of Global Policy	In charge of company response to Index data request and present in the Foundation's company events.
Merck	Former Head of CSR	Member of stakeholder roundtable for Index 2008 and ERC for Index 2010
World Health Organization	Former Team Coordinator – Medicines Information and Evidence for Policy Unit	Member of ERC for Index 2008, 2010, 2012 and 2014 – reviewer for Index 2010, 2012 and 2014
DFID	Former economic adviser	Member of ERC for Index 2008, 2010, 2012
Meteos	Co-founder and partner – formerly SustainAbility	Member of stakeholder roundtable for Index 2008 and ERC Chair for Index 2010 and 2012

## Appendix II – Expert Review Committee for Index 2016

One representative for each of the following organizations:

- World Health Organization (WHO)
- International Federation of Pharmaceutical Associations (IFPMA)
- The World Bank
- Harvard Medical School
- Community Health and Information Network (CHAIN) for Uganda
- Indian Pharmaceutical Alliance
- BNP Paribas Investment Partners
- Independent chair (former WHO)

## Appendix III – Sample indicator followed by its scoring guidelines (Index 2016 final report p. 179)

### E.I.1 Competition: Patent filing (60%)

The company commits to not filing for or enforcing patents related to diseases within the Index scope in Least Developed Countries (LDCs), low-income countries (LICs), and in a subset of lower-middle income countries (LMICs) and upper-middle income countries (UMICs).

- 5 The company makes a public commitment not to patent, not to enforce, or to abandon existing patents relating to products for diseases in the Index scope in all LDCs, LICs, and a subset of LMICs and UMICs.
  - 4 The company makes a public commitment not to patent, not to enforce, or to abandon existing patents relating to products for diseases in the Index scope in all LDCs, LICs, and a subset of LMICs.
  - 3 The company makes a public commitment not to patent, not to enforce, or to abandon existing patents relating to products for diseases in the Index scope in LDCs and/or LICs.
  - 2 The company makes a public commitment not to patent, not to enforce, or to abandon existing patents for a subset of products in the Index scope in a specific region or regions (e.g., LDCs, sub-Saharan Africa, etc.)
  - 1 The company discloses via the Index a clear policy not to patent, not to enforce, or to abandon existing patents relating to specific disease types or products in the Index scope, or in specific regions (e.g., LDCs, sub-Saharan Africa).
- o The company makes no commitment in this area.